US-PAT-NO: 5749851

DOCUMENT-IDENTIFIER: US 5749851 A
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TITLE: Stent installation method using balloon catheter having stepped compliance curve

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Abstract Text - ABTX (1):
A method for installing a stent in a vessel utilizes a single balloon catheter for both low pressure predilation at a relatively small diameter to open the lesion sufficiently to allow insertion and deployment of the stent across the lesion and for subsequent high pressure embedding of the stent in the vessel wall. The same balloon catheter may also be employed to insert and deploy the stent. The balloons utilized in the method have a stepped compliance curve which allows for predilation at a low pressure and predetermined diameter and for high pressure embedding at a substantially larger diameter. The balloons may be provided with a configuration in which only a portion of the balloon has a stepped compliance curve while a further portion has a generally linear compliance profile. With such balloons high pressure treatment of the vessel wall areas not reinforced by the stent can be avoided despite the occurence of longitudinal shrinkage of the stent during expansion thereof.

TITLE - TI (1):
Stent installation method using balloon catheter having

stepped **compliance**
curve

Brief Summary Text - BSTX (4):
Recently the use of a catheter delivered stent to prevent an opened lesion from reclosing or to reinforce a weakened vessel segment, such as an aneurism, has become a common procedure. A typical procedure for stent installation involves performing an initial angioplasty to open the vessel to a predetermined diameter sufficent to permit passage of a stent delivery catheter across the lesion, removal of the angioplasty balloon catheter, insertion of a delivery catheter carrying the stent and a stent deploying mechanism, deploying the stent across the opened lesion so as to seperate the stent from the catheter and bring it into contact with the vessel wall, usually with dilation to a larger diameter using a balloon larger than the balloon of the predilation catheter, and then removing the delivery catheter (after deflating the balloon if used). In many cases it has become the practice to then "retouch" the dilation by deploying a third catheter carrying a balloon capable of dilating at a substantially higher pressure to drive the stent into the vessel wall, thereby to assure that there is no risk of the stent later shifting its position and to reduce occurance of restenosis or thrombus formation. This third "retouch" dilation is often considered necessary when the **balloon** used to seat the stent is made of a **compliant** material because such **balloons** generally cannot be safely pressurized above 9-12 atm., and higher pressures are generally considered necessary to assure full uniform lesion dilation and seating of the stent.

Brief Summary Text - BSTX (6):
In U.S. Pat. No. 5,348,538, incorporated herein by reference, there is described a single layer **balloon** which follows a stepped **compliance** curve. The stepped **compliance** curves of these **balloons** has a lower pressure segment following a first generally linear profile, a transition region, typically in the 8-14 atm range, during which the **balloon** rapidly expands yielding inelastically, and a higher pressure region in which the **balloon** expands along a generally linear, low **compliance** curve. The stepped **compliance** curve allows a physician to dilate different sized lesions without using multiple **balloon** catheters.

Brief Summary Text - BSTX (7):
Stepped **compliance** curve catheter **balloon** devices using two different coextensively mounted **balloon** portions of different initial inflated diameter, are also described in co-pending U.S. Pat. No. application 08/243,473, filed May 16, 1994 as a continuation of now abandoned U.S. Pat. No. application 07/927,062, filed Aug. 8, 1992, and in U.S. Pat. No. Pat. No. 5,358,487 to Miller. These dual layer **balloons** are designed with the outer **balloon** portion larger than the inner portion so that the **compliance** curve follows the inner **balloon** portion until it reaches burst diameter and then, after the inner **balloon** bursts, the outer **balloon** becomes inflated and can be expanded to a larger diameter than the burst diameter of the inner **balloon**.

Brief Summary Text - BSTX (8):
A polyethylene ionomer **balloon** with a stepped **compliance** curve is disclosed in EP 540 858. The reference suggests that the balloon can

be used on stent
delivery catheters. The disclosed **balloon** material of this reference, however,
yields a **compliant balloon** and therefore a stent delivered with such a **balloon**
would typically require "retouch."

Brief Summary Text - BSTX (10):
The invention in one aspect is directed to a method for method for
installing a stent in a vessel utilizes a single balloon catheter for both low
pressure predilation at a relatively small diameter to open the lesion
sufficiently to allow insertion and deployment of the stent across the lesion
and for subsequent high pressure embedding of the stent in the vessel wall.
The same balloon catheter may also be employed to insert and deploy the stent.
Thus at least one catheter may be eliminated from what has heretofore been a
two or three catheter installation process. The **balloons** utilized in the
method have a stepped **compliance** curve which allows for predilation at a low
pressure and predetermined diameter and for high pressure embedding at a
substantially larger diameter.

Brief Summary Text - BSTX (11):
In a further aspect of the invention novel **balloon** structures having high
wall strengths, high burst pressures and low **compliance** are provided in which a
first portion of the **balloon** body has a generally linear **compliance** curve and a
second portion of the **balloon** body has a stepped **compliance** curve. Both
portions of the balloon are configured to have essentially the same diameter at
low pressure so that the entire balloon may be used to predilate a lesion.
However at higher pressure the configuration of the balloon changes due to

rapid expansion of the second balloon portion. At still higher pressures the
compliance curve of the second portion levels off to a low **compliance** profile
so that this portion of the **balloon** can be used for high pressure embedment of
the stent without substantially increasing the stent size. With such balloons,
exposure of the vessel wall areas which are not reinforced by the stent to high
pressure can be avoided, despite the typically shorter length of conventional
stents than the typical length of predilation balloons.

Drawing Description Text - DRTX (2):
FIG. 1 is a longitudinal sectional view of a vessel showing an angioplasty
catheter, not in section and having a stepped **compliance** curve **balloon** on the
distal end thereof, inserted in the vessel and predilating a lesion in the
vessel.

Drawing Description Text - DRTX (11):
FIG. 10 is a graph showing the **compliance** curves of several **balloons** of the
type shown in FIGS. 1, 3 and 4 compared to a conventional 3.5 mm angioplasty
balloon of the same material.

Drawing Description Text - DRTX (12):
FIG. 11 is a graph of the **compliance** curves of a **balloon** of the type shown
in FIG. 6.

Detailed Description Text - DETX (2):
The catheters employed in the practice of the present invention are most
conveniently constructed as over-the-wire **balloon** catheters of conventional
form for use in angioplasty, except that the **balloon** has a stepped **compliance**
curve. However it should be understood that the present

invention can be applied, in addition to over-the-wire catheters, to fixed-wire catheters, to shortened guide wire lumens or single operator exchange catheters, and to non over-the-wire balloon catheters. Furthermore this invention can be used with balloon catheters intended for use in any and all vascular systems or cavities of the body.

Detailed Description Text - DETX (3):

Referring to FIGS. 1-5, the process of the invention is illustrated by these Figures. In FIG. 1, a catheter 10 carrying a balloon 12 on the distal end thereof has been inserted over guide wire 13 into a vessel 14 and fed to a lesion 16 where it is used to predilate the lesion to a predetermined diameter, typically about 2.5 mm. In the process of the invention, **balloon** 12 is made of a high strength polymer, such as PET and has a stepped **compliance** curve, the predilation diameter is below the transition region on that curve and the desired final dilated diameter, typically 2.75-4.0 mm, lies on the portion of the curve above the transition region. After the predilation the balloon is deflated and the catheter 10 is removed from the vessel 14.

Detailed Description Text - DETX (6):

Alternatively, catheter 10 may be employed as a delivery catheter. In the specific embodiment illustrated in FIGS. 3-4, an unexpanded stent 18 has been mounted on the catheter 10 over balloon 12 after catheter 10 has been used to predilate the lesion and has been removed from the lesion. Catheter 10 is then reinserted into the vessel 14 and located across the lesion (FIG. 3). Balloon 12 is then reinflated as shown in FIG. 4 to expand and install the stent 18 and to dilate the lesion. The pressure employed is one which

inflates the balloon
to a diameter above the transition region and therefore the same balloon as
used in predilation can be used to deliver the catheter and dilate the lesion.
Further, because the **balloon** 12 follows a low **compliance** curve above the
transition region, the pressure can safely be increased above 12 atm so as to
firmly seat stent 18 without having to undergo "retouch." Typically the **balloon**
12 will be capable of inflation to at least as high as 20 atm.

Detailed Description Text - DETX (9):

The stepped **compliance** curve **balloons** should be made of a thermoplastic
polymer material which has a high strength, and gives a low **compliance balloon**
at pressures above about 15 atmospheres. For purposes of this application "low
compliance" is considered to correspond to a diameter increase of no more than
0.1 mm per increased atmosphere of pressure, preferably less than 0.06 **mm/atm**.
Suitably the balloon polymer is poly(ethylene terephthalate) (PET) of initial
intrinsic viscosity of at least 0.5, more preferably 0.7-0.9. Other high
strength polyester materials, such as poly(ethylene napthalenedicarboxylate)
(PEN), nylons such as nylon 11 or nylon 12, thermoplastic polyimides and high
strength engineering thermoplastic polyurethanes such as Isoplast 301 sold by
Dow Chemical Co., are considered suitable alternative materials. Desirably the
balloon is blown in a way which will give a wall strength of at least 18,000
psi, preferably greater than 20,000 psi. Techniques for manufacturing balloons
with such wall strengths are well known.

Detailed Description Text - DETX (10):

After being blown, the **balloon** is provided with a stepped **compliance** curve

by annealing the **balloon** for a-short time after blowing at a pressure at or only slightly above ambient and at a temperature which causes the blown **balloon** to shrink. The process is described in U.S. Pat. No. 5,348,538. However, the **balloons** of the invention are desirably constructed with a greater difference between the low pressure and high pressure linear regions of the **compliance** curve so that the transition between the two regions results in a step-up of diameter of the **balloon** of at least 0.4 mm. This is accomplished by blowing the balloon to the larger diameter and then shrinking to a greater extent than was done in the specific illustrative examples of U.S. Pat. No. 5,348,538. The amount of shrinkage is controlled by the pressure maintained in the balloon during annealing and the temperature and time of the annealing.
For a balloon made from 0.74 intrinsic viscosity PET, the blowing pressure is suitably in the range 200-400 psi, and temperature is suitably in the range of 90.degree.-100.degree. C. and the annealing pressure is in the range of 0-20, preferably 5-10 psi at 90.degree.-100.degree. C. for 3-10 seconds.

Detailed Description Text - DETX (11):
In a further aspect of the invention, the **balloons** employed in the inventive process are configured so that a first portion of the body of the **balloon** has a stepped **compliance** curve and the remainder of the **balloon** has an unstepped **compliance** curve, the low pressure regions of the **compliance** curves of both the first portion and the remainder portion(s) being generally collinear. By this means the length of the balloon which will expand and seat the stent will be smaller than the length which is used to accomplish predilation. Since many

stents are in the 7-10 mm length range whereas predilation balloons are desirably 15-20 mm or even longer, this shorter configuration for the portion which will step-up to a larger diameter ("hyper-extend") is desirable so that the hyper-extension will not overlap tissue which is unreinforced by the stent. Two balloons of this preferred configuration are shown, mounted on catheters, in FIGS. 6 and 8.

Detailed Description Text - DETX (12):

In FIG. 6, the balloon 30 is shown in its fully expanded high pressure configuration, mounted on a catheter 28. As shown schematically in FIG. 7, this balloon is blown in a mold of the general shape of the balloon in FIG. 6 and then the annealing step is performed on the enlarged portion 32 by dipping the balloon in the direction indicated by arrows 36 to level A in a bath of heated water or other suitable heated fluid while the balloon is pressurized at low pressure, for instance 0-10 psi, so that only portion 32 is annealed. After annealing portion 32 will be shrunken so that, the configuration of the balloon will be substantially linear and will expand generally linearly until pressurized above about 8-12 atm. At higher pressures, the portion 34 of balloon 30 will continue to expand along the same generally linear curve but portion 32 will rapidly expand until the balloon configuration is restored to shape shown in FIG. 6, after which the expansion profile of portion 32 will level out again to a noncompliant curve but at a substantial increase in absolute diameter relative to the diameter of portion 34. **Balloons** of this configuration, have been used to produce **compliance** curves as shown in FIG. 11.

Detailed Description Text - DETX (16):
Referring now to the graph shown in FIG. 10, in which pressure in atmospheres is plotted on the x-axis and balloon diameter in millimeters is plotted on the y-axis. The **compliance** curves of several **balloons** have been manufactured in accordance with U.S. Pat. No. 5,348,538 and useful in the practice of this invention have been plotted on this graph and compared to a conventional 3.5 mm angioplasty balloon Q of the same PET material. The stepped **compliance** curve **balloons,** X, Y and Z, plotted on this graph had nominal diameters prior to being shrunk of 3.0, 3.5 and 4.0 millimeters, respectively.

Detailed Description Text - DETX (17):
FIG. 11 is a graph of the **compliance** curves of a **balloon** of the type shown as **balloon** 30 in FIG. 6. Curve 11a is the **compliance** curve of portion 32 of **balloon** 30 and curve 11b is the **compliance** curve of the portion 34 of **balloon** 30. The balloon was made from PET of 0.74 intrinsic viscosity and, after blowing had a body wall thickness of 0.0013 inches. Portion 32 thereof was annealed by dipping in a 95.degree. C. water bath for 5 seconds, while pressurized at 10 atm pressure, to shrink portion 32 to the diameter of portion 34. The **balloon** was then mounted on a catheter and the **compliance** curve obtained by incrementally inflating the **balloon** until burst, measuring the diameter of both portions 32 and 34 at each incremental pressure.

Detailed Description Text - DETX (19):
The invention may also be practiced by use of dual layer balloons such as described in co-pending U.S. Pat. No. application

08/243,473, filed May 16,
1994 as a continuation of now abandoned U.S. Pat. No.
application 07/927,062,
filed Aug. 8, 1992, incorporated herein by reference, and
in U.S. Pat. No.
Pat. 5,358,487, incorporated herein by reference.
Suitably both **balloons** of
the dual layer **balloons** are low **compliance balloons**
designed with the outer
balloon portion larger by at least 0.25 mm than the inner
portion and the inner
balloon designed to burst at a pressure below about 15 atm
so that the
compliance curve follows the inner **balloon** portion until it
reaches burst
diameter and then, after the inner **balloon** bursts, the
outer **balloon** becomes
inflated and can be expanded to a larger diameter than the
burst diameter of
the inner **balloon**.

Claims Text - CLTX (1):

1. A **balloon** for a dilation procedure, the **balloon**
having first and second
adjacent body longitudinal portions the first body portion
having a generally
linear **compliance** curve to burst pressure and the second
body portion having a
stepped **compliance** curve characterized by a low pressure
segment defined by a
low inflation pressure range, said low pressure segment
being generally
collinear with a corresponding segment of the **compliance**
curve of the first
body portion which is defined by said low inflation
pressure range, a
transition segment during which the **balloon** expands rapidly
relative to the
first body portion and a high pressure segment during which
the **compliance**
curve of the second portion expands slowly relative to the
transition region.

Claims Text - CLTX (3):

3. A **balloon** as in claim 1 wherein when the **balloon** is

inflated to a
pressure of 6 atm the second body portion is on the low
pressure segment of its
compliance curve and when the **balloon** is inflated to 15 atm
the second body
portion is on the high pressure segment of its **compliance**
curve.

Claims Text - CLTX (5):
5. A **balloon** as in claim 1 wherein the **balloon** further
comprises a third
body portion adjacent the second body portion so that the
second body portion
lies between the first and third body portions, the third
body portion having a
compliance curve which is generally linear to burst and
generally collinear
with the **compliance** curve of the first body portion to
burst.

Claims Text - CLTX (9):
9. A **balloon** as in claim 1 wherein the high pressure
segment has a
compliance curve according to which the **balloon** expands at
a rate of no more
than 0.1 **mm/atm** from 15 atm to burst.

Claims Text - CLTX (10):
10. A **balloon** as in claim 9 wherein according to said
high pressure
compliance curve the **balloon** expands at a rate no more than
is no more than
0.06 **mm/atm** from 15 atm to burst.

US005749851A

United States Patent [19]

Wang

[11] **Patent Number: 5,749,851**

[45] **Date of Patent: May 12, 1998**

[54] **STENT INSTALLATION METHOD USING BALLOON CATHETER HAVING STEPPED COMPLIANCE CURVE**

[75] Inventor: **Lixiao Wang**, Maple Grove, Minn.

[73] Assignee: **Scimed Life Systems, Inc.**, Maple Grove, Minn.

[21] Appl. No.: **397,615**

[22] Filed: **Mar. 2, 1995**

[51] **Int. Cl.**^{6} **A61M 29/00**

[52] **U.S. Cl.** **604/96**; 604/101

[58] **Field of Search** 604/96, 97, 98, 604/99, 100, 101, 102, 103; 606/192, 193, 194, 195, 196

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94/02193	3/1994	WIPO .

Primary Examiner—Sam Rimell
Attorney, Agent, or Firm—Vidas, Arrett & Steinkraus, P.A.

[57] **ABSTRACT**

A method for installing a stent in a vessel utilizes a single balloon catheter for both low pressure predilation at a relatively small diameter to open the lesion sufficiently to allow insertion and deployment of the stent across the lesion and for subsequent high pressure embedding of the stent in the vessel wall. The same balloon catheter may also be employed to insert and deploy the stent. The balloons utilized in the method have a stepped compliance curve which allows for predilation at a low pressure and predetermined diameter and for high pressure embedding at a substantially larger diameter. The balloons may be provided with a configuration in which only a portion of the balloon has a stepped compliance curve while a further portion has a generally linear compliance profile. With such balloons high pressure treatment of the vessel wall areas not reinforced by the stent can be avoided despite the occurence of longitudinal shrinkage of the stent during expansion thereof.

16 Claims, 5 Drawing Sheets

Fig.1

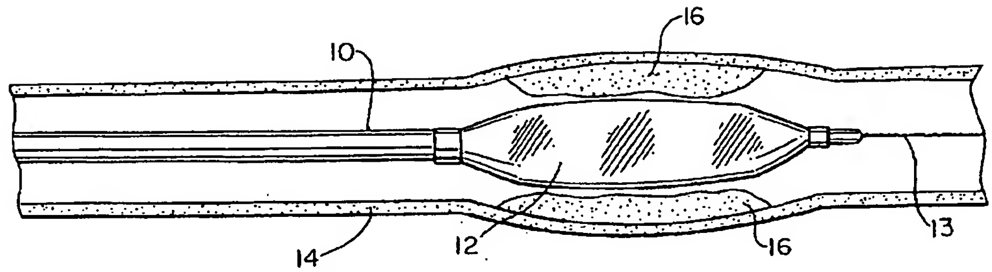

Fig.2

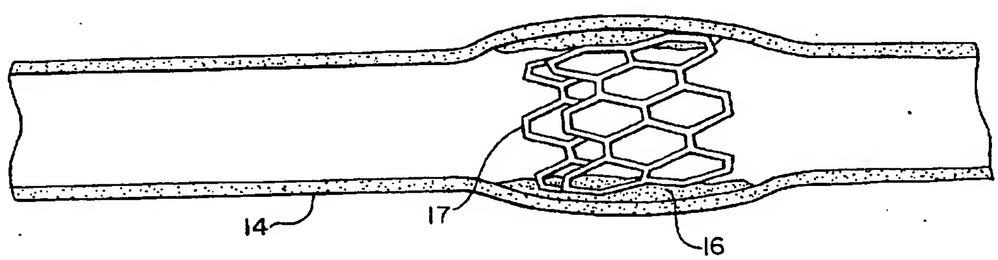

Fig.3

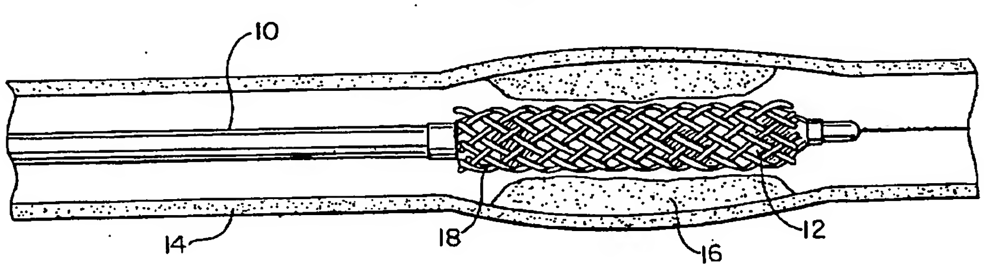

Fig.4

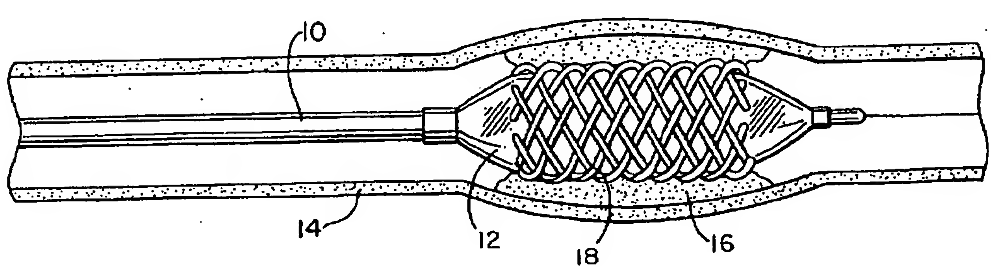

Fig.5

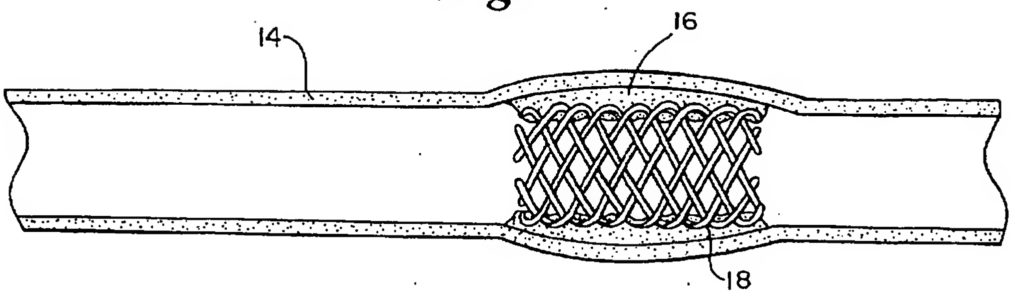

Fig.6

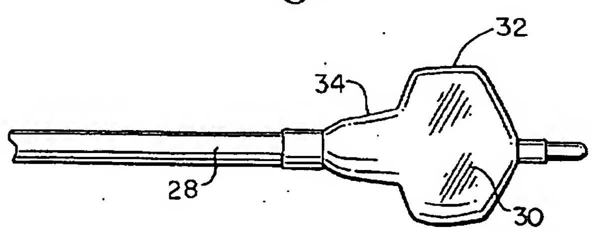

Fig.8

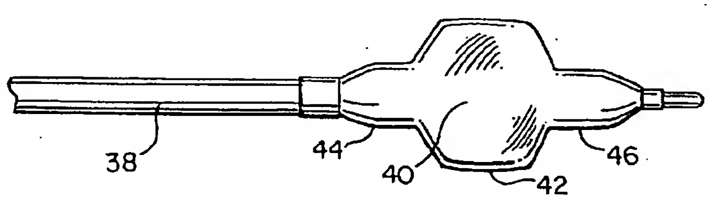

Fig. 7

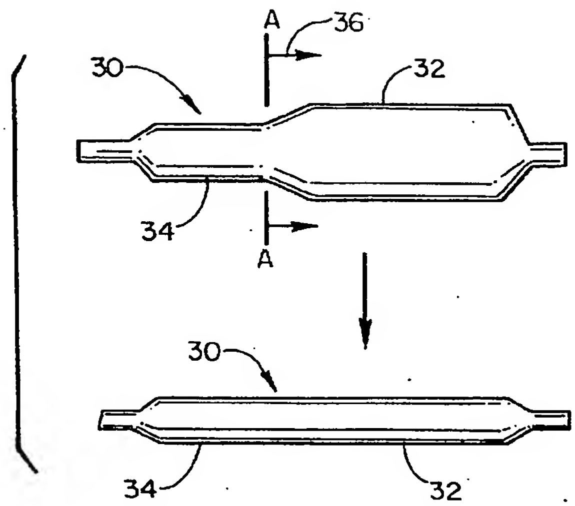

Fig. 9

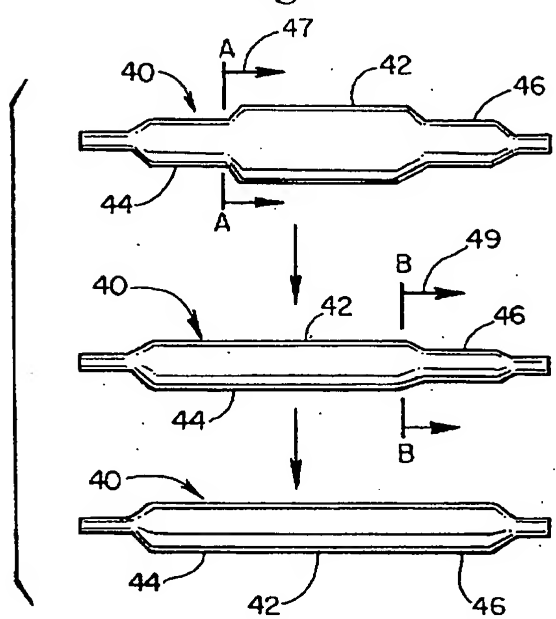

Fig.10

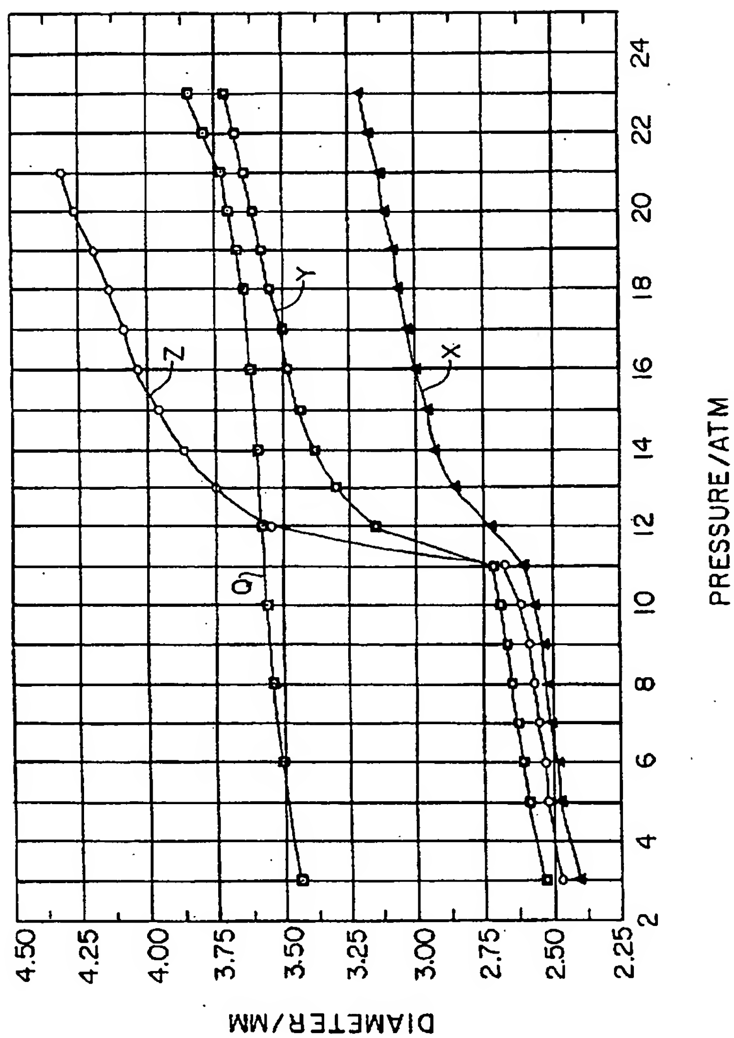
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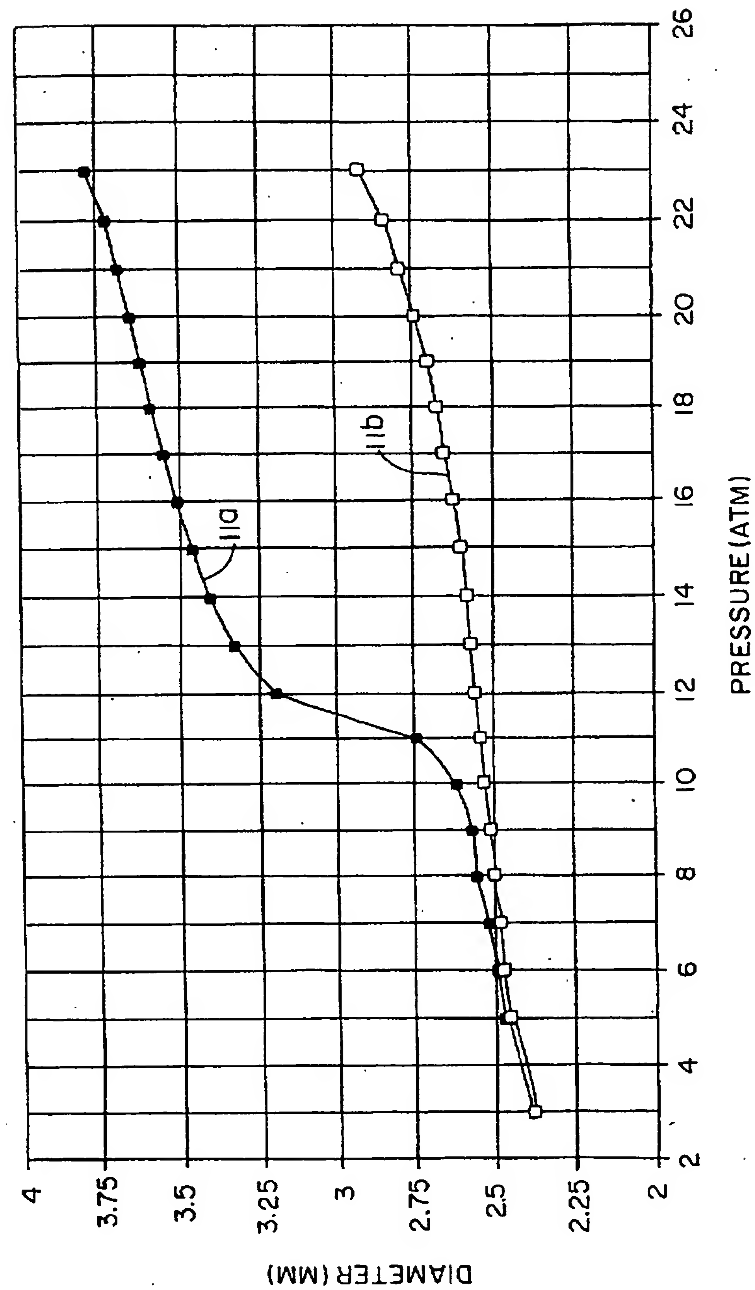
Fig.11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4

STENT INSTALLATION METHOD USING BALLOON CATHETER HAVING STEPPED COMPLIANCE CURVE

BACKGROUND OF THE INVENTION

The present invention relates generally to a method of installing a stent utilizing a balloon catheter to perform an initial angioplasty and to seat the stent after it has been located in the vessel. The invention also relates to novel balloon structures which have particular use in the method of the invention.

Angioplasty, an accepted and well known medical practice involves inserting a balloon catheter into the blood vessel of a patient, maneuvering and steering the catheter through the patient's vessels to the site of the lesion with the balloon in an uninflated form. The uninflated balloon portion of the catheter is located within the blood vessel such that it crosses the lesion or reduced area. Pressurized inflation fluid is metered to the inflatable balloon through a lumen formed in the catheter to thus dilate the restricted area. The inflation fluid is generally a liquid and is applied at relatively high pressures, usually in the area of six to twenty atmospheres. As the balloon is inflated it expands and forces open the previously closed area of the blood vessel. Balloons used in angioplasty procedures such as this are generally fabricated by molding and have predetermined design dimensions such as length, wall thickness and nominal diameter. Balloon catheters are also used in other systems of the body for example the prostate and the urethra. Balloon catheters come in a large range of sizes and must be suitably dimensioned for their intended use.

Recently the use of a catheter delivered stent to prevent an opened lesion from reclosing or to reinforce a weakened vessel segment, such as an aneurism, has become a common procedure. A typical procedure for stent installation involves performing an initial angioplasty to open the vessel to a predetermined diameter sufficent to permit passage of a stent delivery catheter across the lesion, removal of the angioplasty balloon catheter, insertion of a delivery catheter carrying the stent and a stent deploying mechanism, deploying the stent across the opened lesion so as to seperate the stent from the catheter and bring it into contact with the vessel wall, usually with dilation to a larger diameter using a balloon larger than the balloon of the predilation catheter, and then removing the delivery catheter (after deflating the balloon if used). In many cases it has become the practice to then "retouch" the dilation by deploying a third catheter carrying a balloon capable of dilating at a substantially higher pressure to drive the stent into the vessel wall, thereby to assure that there is no risk of the stent later shifting its position and to reduce occurance of restenosis or thrombus formation. This third "retouch" dilation is often considered necessary when the balloon used to seat the stent is made of a compliant material because such balloons generally cannot be safely pressurized above 9–12 atm., and higher pressures are generally considered necessary to assure full uniform lesion dilation and seating of the stent.

A wide variety of stent configurations and deployment methods are known. For instance, stent configurations include various forms of bent wire devices, self-expanding stents; stents which unroll from a wrapped configuration on the catheter; and stents which are made of a deformable material so that the device may be deformed on deployment from a small diameter to a larger diameter configuration. References disclosing stent devices and deployment catheters include:

U.S. Pat. No. 4733665	Palmaz
U.S. Pat. No. 4776337	Palmaz
U.S. Pat. No. 5195984	Schatz
U.S. Pat. No. 5234457	Andersen
U.S. Pat. No. 5116360	Pinchuck et al
U.S. Pat. No. 5116318	Hillstead
U.S. Pat. No. 4649922	Wiktor
U.S. Pat. No. 4655771	Wallsten
U.S. Pat. No. 5089006	Stiles
U.S. Pat. No. 5007926	Derbyshire
U.S. Pat. No. 4705517	DiPisa, Jr
U.S. Pat. No. 4740207	Kreamer
U.S. Pat. No. 4877030	Beck et al
U.S. Pat. No. 5108417	Sawyer
U.S. Pat. No. 4923464	DiPisa, Jr
U.S. Pat. No. 5078726	Kreamer
U.S. Pat. No. 5171262	MacGregor
U.S. Pat. No. 5059211	Stack et al
U.S. Pat. No. 5104399	Lazarus
U.S. Pat. No. 5104404	Wolff
U.S. Pat. No. 5019090	Pinchuk
U.S. Pat. No. 4954126	Wallsten
U.S. Pat. No. 4994071	MacGregor
U.S. Pat. No. 4580568	Gianturco
U.S. Pat. No. 4969890	Sugita et al
U.S. Pat. No. 4795458	Regan
U.S. Pat. No. 4760849	Kropf
U.S. Pat. No. 5192297	Hull
U.S. Pat. No. 4681110	Wiktor
U.S. Pat. No. 4800882	Gianturco
U.S. Pat. No. 4830003	Wolff et al
U.S. Pat. No. 4856516	Hillstead
U.S. Pat. No. 4922905	Strecker
U.S. Pat. No. 4886062	Wiktor
U.S. Pat. No. 4907336	Gianturco
U.S. Pat. No. 4913141	Hillstead
U.S. Pat. No. 5092877	Pinchuk
U.S. Pat. No. 5123917	Lee
U.S. Pat. No. 5116309	Coll
U.S. Pat. No. 5122154	Rhodes
U.S. Pat. No. 5133732	Wiktor
U.S. Pat. No. 5135536	Hillstead
U.S. Pat. No. 5282824	Gianturco
U.S. Pat. No. 5292331	Boneau
U.S. Pat. No. 5035706	Gianturco et al
U.S. Pat. No. 5041126	Gianturco
U.S. Pat. No. 5061275	Wallsten et al
U.S. Pat. No. 5064435	Porter
U.S. Pat. No. 5092841	Spears
U.S. Pat. No. 5108416	Ryan et al
U.S. Pat. No. 4990151	Wallsten
U.S. Pat. No. 4990155	Wilkoff
U.S. Pat. No. 5147385	Beck et al
U.S. Pat. No. 5163952	Froix

In U.S. Pat. No. 5,348,538, incorporated herein by reference, there is described a single layer balloon which follows a stepped compliance curve. The stepped compliance curves of these balloons has a lower pressure segment following a first generally linear profile, a transition region, typically in the 8–14 atm range, during which the balloon rapidly expands yielding inelastically, and a higher pressure region in which the balloon expands along a generally linear, low compliance curve. The stepped compliance curve allows a physician to dilate different sized lesions without using multiple balloon catheters.

Stepped compliance curve catheter balloon devices using two different coextensively mounted balloon portions of different initial inflated diameter, are also described in co-pending U.S. Pat. No. application 08/243,473, filed May 16, 1994 as a continuation of now abandoned U.S. Pat. No. application 07/927,062, filed Aug. 8, 1992, and in U.S. Pat. No. Pat. No. 5,358,487 to Miller. These dual layer balloons are designed with the outer balloon portion larger than the inner portion so that the compliance curve follows the inner balloon portion until it reaches burst diameter and then, after

the inner balloon bursts, the outer balloon becomes inflated and can be expanded to a larger diameter than the burst diameter of the inner balloon.

A polyethylene ionomer balloon with a stepped compliance curve is disclosed in EP 540 858. The reference suggests that the balloon can be used on stent delivery catheters. The disclosed balloon material of this reference, however, yields a compliant balloon and therefore a stent delivered with such a balloon would typically require "retouch."

SUMMARY OF THE INVENTION

The invention in one aspect is directed to a method for method for installing a stent in a vessel utilizes a single balloon catheter for both low pressure predilation at a relatively small diameter to open the lesion sufficiently to allow insertion and deployment of the stent across the lesion and for subsequent high pressure embedding of the stent in the vessel wall. The same balloon catheter may also be employed to insert and deploy the stent. Thus at least one catheter may be eliminated from what has heretofore been a two or three catheter installation process. The balloons utilized in the method have a stepped compliance curve which allows for predilation at a low pressure and predetermined diameter and for high pressure embedding at a substantially larger diameter.

In a further aspect of the invention novel balloon structures having high wall strengths, high burst pressures and low compliance are provided in which a first portion of the balloon body has a generally linear compliance curve and a second portion of the balloon body has a stepped compliance curve. Both portions of the balloon are configured to have essentially the same diameter at low pressure so that the entire balloon may be used to predilate a lesion. However at higher pressure the configuration of the balloon changes due to rapid expansion of the second balloon portion. At still higher pressures the compliance curve of the second portion levels off to a low compliance profile so that this portion of the balloon can be used for high pressure embedment of the stent without substantially increasing the stent size. With such balloons, exposure of the vessel wall areas which are not reinforced by the stent to high pressure can be avoided, despite the typically shorter length of conventional stents than the typical length of predilation balloons.

The novel balloons of the invention are made by molding a balloon into a configuration in which the second portion has a larger diameter than the first portion and then shrinking the second portion to the diameter of the first portion. The method of making such balloons comprises yet another aspect of the invention.

These and other aspects and advantages of the present invention will no doubt become apparent to those skilled in the art after having read the following detailed description of the invention as illustrated by the various drawing figures.

BRIEF DESCRIPTION OF DRAWINGS

FIG. 1 is a longitudinal sectional view of a vessel showing an angioplasty catheter, not in section and having a stepped compliance curve balloon on the distal end thereof, inserted in the vessel and predilating a lesion in the vessel.

FIG. 2 is a view of a vessel as in FIG. 1 after installation of a stent but before a "retouch" procedure.

FIG. 3 is a view as in FIG. 1 in which after predilation and with the same catheter, now carrying a stent mounted over the balloon, reinserted to deliver the stent to the lesion.

FIG. 4 is a view as in FIG. 3 with the balloon expanded to install the stent and further dilate the lesion.

FIG. 5 is a view as in FIG. 3 after completion of the procedure of FIG. 3.

FIG. 6 is a side view the distal end of a catheter having an alternate balloon of the invention, shown in hyper-extended form.

FIG. 7 is a schematic illustration depicting the process stages for preparing a balloon as in FIG. 6.

FIG. 8 is a view of a catheter as in FIG. 6 except that a second alternate balloon of the invention is depicted.

FIG. 9 is a schematic illustration depicting the process stages for preparing a balloon as in FIG. 8.

FIG. 10 is a graph showing the compliance curves of several balloons of the type shown in FIGS. 1, 3 and 4 compared to a conventional 3.5 mm angioplasty balloon of the same material.

FIG. 11 is a graph of the compliance curves of a balloon of the type shown in FIG. 6.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The catheters employed in the practice of the present invention are most conveniently constructed as over-the-wire balloon catheters of conventional form for use in angioplasty, except that the balloon has a stepped compliance curve. However it should be understood that the present invention can be applied, in addition to over-the-wire catheters, to fixed-wire catheters, to shortened guide wire lumens or single operator exchange catheters, and to non over-the-wire balloon catheters. Furthermore this invention can be used with balloon catheters intended for use in any and all vascular systems or cavities of the body.

Referring to FIGS. 1–5, the process of the invention is illustrated by these Figures. In FIG. 1, a catheter **10** carrying a balloon **12** on the distal end thereof has been inserted over guide wire **13** into a vessel **14** and fed to a lesion **16** where it is used to predilate the lesion to a predetermined diameter, typically about 2.5 mm. In the process of the invention, balloon **12** is made of a high strength polymer, such as PET and has a stepped compliance curve, the predilation diameter is below the transition region on that curve and the desired final dilated diameter, typically 2.75–4.0 mm, lies on the portion of the curve above the transition region. After the predilation the balloon is deflated and the catheter **10** is removed from the vessel **14**.

The next step is to deliver the stent to the lesion. In a first embodiment of the process, a separate stent delivery catheter of any conventional type is used to deliver the stent to the lesion, install the stent in place across the lesion, and further dilate the lesion to a larger diameter, typically 2.75–4.0 mm. The delivery catheter is then withdrawn to leave the stent **17** in place across the dilated lesion, as shown in FIG. 2. Occasionally as indicated in FIG. 2 the stent is not fully seated or can move somewhat after installation if the installation process is discontinued at this point.

To assure that the stent is firmly seated in the lesion so that it cannot move and to additionally reduce occurances of restenosis and thrombus formation, in this embodiment of the inventive process, after the delivery catheter has been removed, catheter **10** is reinserted and expanded to a retouch pressure, typically above 9 atm and preferably in the range of 12–20 atm.

Alternatively, catheter **10** may be employed as a delivery catheter. In the specific embodiment illustrated in FIGS.

3-4, an unexpanded stent **18** has been mounted on the catheter **10** over balloon **12** after catheter **10** has been used to predilate the lesion and has been removed from the lesion. Catheter **10** is then reinserted into the vessel **14** and located across the lesion (FIG. 3). Balloon **12** is then reinflated as shown in FIG. 4 to expand and install the stent **18** and to dilate the lesion. The pressure employed is one which inflates the balloon to a diameter above the transition region and therefore the same balloon as used in predilation can be used to deliver the catheter and dilate the lesion. Further, because the balloon **12** follows a low compliance curve above the transition region, the pressure can safely be increased above 12 atm so as to firmly seat stent **18** without having to undergo "retouch." Typically the balloon **12** will be capable of inflation to at least as high as 20 atm.

FIG. 5 depicts the stent **18** in place after high pressure dilation. A similar result is obtained if the catheter **10** is used for predilation and for "retouch" but not for stent installation. It should be noted that the specific configuration of the stents **17** and **18** is not critical and two different configurations have been depicted merely to indicate that different configurations may be employed in either embodiment of the inventive installation process. The particular configurations employed may be reversed or another stent configuration, including balloon expandable stents and self-expandable stents, may be substituted without departing from the invention hereof.

Thus unlike the prior art methods for accomplishing the same sequences of predilation, stent delivery/dilation and high pressure seating or "retouch," a separate catheter is not required to be used in the final high pressure seating step from the catheter used in the predilation step. This significantly reduces the cost of the procedure, since the catheter costs are a significant part of the overall cost of the procedure.

The stepped compliance curve balloons should be made of a thermoplastic polymer material which has a high strength, and gives a low compliance balloon at pressures above about 15 atmospheres. For purposes of this application "low compliance" is considered to correspond to a diameter increase of no more than 0.1 mm per increased atmosphere of pressure, preferably less than 0.06 mm/atm. Suitably the balloon polymer is poly(ethylene terephthalate) (PET) of initial intrinsic viscosity of at least 0.5, more preferably 0.7–0.9. Other high strength polyester materials, such as poly(ethylene napthalenedicarboxylate) (PEN), nylons such as nylon 11 or nylon 12, thermoplastic polyimides and high strength engineering thermoplastic polyurethanes such as Isoplast 301 sold by Dow Chemical Co., are considered suitable alternative materials. Desirably the balloon is blown in a way which will give a wall strength of at least 18,000 psi, preferably greater than 20,000 psi. Techniques for manufacturing balloons with such wall strengths are well known.

After being blown, the balloon is provided with a stepped compliance curve by annealing the balloon for a short time after blowing at a pressure at or only slightly above ambient and at a temperature which causes the blown balloon to shrink. The process is described in U.S. Pat. No. 5,348,538. However, the balloons of the invention are desirably constructed with a greater difference between the low pressure and high pressure linear regions of the compliance curve so that the transition between the two regions results in a step-up of diameter of the balloon of at least 0.4 mm. This is accomplished by blowing the balloon to the larger diameter and then shrinking to a greater extent than was done in the specific illustrative examples of U.S. Pat. No. 5,348,538. The amount of shrinkage is controlled by the pressure maintained in the balloon during annealing and the temperature and time of the annealing. For a balloon made from 0.74 intrinsic viscosity PET, the blowing pressure is suitably in the range 200–400 psi, and temperature is suitably in the range of 90°–100° C. and the annealing pressure is in the range of 0–20, preferably 5–10 psi at 90°–100° C. for 3–10 seconds.

In a further aspect of the invention, the balloons employed in the inventive process are configured so that a first portion of the body of the balloon has a stepped compliance curve and the remainder of the balloon has an unstepped compliance curve, the low pressure regions of the compliance curves of both the first portion and the remainder portion(s) being generally collinear. By this means the length of the balloon which will expand and seat the stent will be smaller than the length which is used to accomplish predilation. Since many stents are in the 7–10 mm length range whereas predilation balloons are desirably 15–20 mm or even longer, this shorter configuration for the portion which will step-up to a larger diameter ("hyper-extend") is desirable so that the hyper-extension will not overlap tissue which is unreinforced by the stent. Two balloons of this preferred configuration are shown, mounted on catheters, in FIGS. **6** and **8**.

In FIG. **6**, the balloon **30** is shown in its fully expanded high pressure configuration, mounted on a catheter **28**. As shown schematically in FIG. **7**, this balloon is blown in a mold of the general shape of the balloon in FIG. **6** and then the annealing step is performed on the enlarged portion **32** by dipping the balloon in the direction indicated by arrows **36** to level A in a bath of heated water or other suitable heated fluid while the balloon is pressurized at low pressure, for instance 0–10 psi, so that only portion **32** is annealed. After annealing portion **32** will be shrunken so that, the configuration of the balloon will be substantially linear and will expand generally linearly until pressurized above about 8–12 atm. At higher pressures, the portion **34** of balloon **30** will continue to expand along the same generally linear curve but portion **32** will rapidly expand until the balloon configuration is restored to shape shown in FIG. **6**, after which the expansion profile of portion **32** will level out again to a noncompliant curve but at a substantial increase in absolute diameter relative to the diameter of portion **34**. Balloons of this configuration, have been used to produce compliance curves as shown in FIG. **11**.

It should be understood that while FIG. **6** shows portion **32** of balloon **30** mounted distally on catheter **28**, balloon **30** may instead be mounted with portion **34** mounted distally without departing from the invention hereof.

If the balloon of FIG. **6** is used to deliver and install the stent, the catheter **28** will have to be backed up a short distance to center portion **32** under the stent after expansion of balloon **30** sufficiently to bring it into contact with the lesion but before the balloon portion **32** is fully expanded to fully dilate the lesion and set the stent. This can be accomplished by providing marker bands (not shown) on the portion of the catheter shaft under the balloon to indicate the proximal and distal boundries of portion **32**.

In the alternate embodiment of FIG. **8**, the balloon **40**, mounted on catheter **38**, has a hyper-extensible portion **42** located centrally on the balloon body. Therefore, after installation of the stent, the high pressure stent setting step can be performed immediately without repositioning the catheter and without risking damage to tissue unreinforced by the stent. This balloon is blown in a mold having a configuration which is substantially the shape shown in FIG. **8**. To anneal

and shrink portion **42** to the diameter of portions **44**, **46**, heating during annealing may be confined to the central portion **42**, suitably by heating with a hot air stream, using baffles to protect the end regions **44**, **46** from the air stream. Alternatively, as shown schematically in FIG. **9**, the balloon **40** is dipped in the direction of arrows **47** to level A in a heated bath to fully immerse portions **42** and **46**, until portion **42** has reached the diameter of portion **44**. At this point portion **46** will be shrunk to a diameter less than portion **44**. Balloon **40** is then dipped into a heated bath in the direction of arrows **49** to level B so that only portion **46** is immersed and then portion **46** is reblown to the diameters of portion **44** and shrunken portion **42**. This reblowing step may be accomplished either with the aid of a mold or by free-blowing.

Referring now to the graph shown in FIG. **10**, in which pressure in atmospheres is plotted on the x-axis and balloon diameter in millimeters is plotted on the y-axis. The compliance curves of several balloons have been manufactured in accordance with U.S. Pat. No. 5,348,538 and useful in the practice of this invention have been plotted on this graph and compared to a conventional 3.5 mm angioplasty balloon Q of the same PET material. The stepped compliance curve balloons, X, Y and Z, plotted on this graph had nominal diameters prior to being shrunk of 3.0, 3.5 and 4.0 millimeters, respectively.

FIG. **11** is a graph of the compliance curves of a balloon of the type shown as balloon **30** in FIG. **6**. Curve **11***a* is the compliance curve of portion **32** of balloon **30** and curve **11***b* is the compliance curve of the portion **34** of balloon **30**. The balloon was made from PET of 0.74 intrinsic viscosity and, after blowing had a body wall thickness of 0.0013 inches. Portion **32** thereof was annealed by dipping in a 95° C. water bath for 5 seconds, while pressurized at 10 atm pressure, to shrink portion **32** to the diameter of portion **34**. The balloon was then mounted on a catheter and the compliance curve obtained by incrementally inflating the balloon until burst, measuring the diameter of both portions **32** and **34** at each incremental pressure.

With regard to definitions, FIG. **11** can be referred to for illustration of what is meant by "generally linear" with reference to the portions of curve **11***a* between 3 and 10 atm and again between about 13 and 26 atm. Curve **11***b* is considered generally linear through out its entire length. "Generally collinear" is considered to encompass divergences between two curves of no more than about 0.2 atm, preferably less than 0.15 mm divergence between the two curves. Curves **11***a* and **11***b* are "generally collinear" in the range from 3 atm to about 10 atm.

The invention may also be practiced by use of dual layer balloons such as described in co-pending U.S. Pat. No. application 08/243,473, filed May 16, 1994 as a continuation of now abandoned U.S. Pat. No. application 07/927,062, filed Aug. 8, 1992, incorporated herein by reference, and in U.S. Pat. No. Pat. 5,358,487, incorporated herein by reference. Suitably both balloons of the dual layer balloons are low compliance balloons designed with the outer balloon portion larger by at least 0.25 mm than the inner portion and the inner balloon designed to burst at a pressure below about 15 atm so that the compliance curve follows the inner balloon portion until it reaches burst diameter and then, after the inner balloon bursts, the outer balloon becomes inflated and can be expanded to a larger diameter than the burst diameter of the inner balloon.

Although the present invention has been described in terms of specific embodiments, it is anticipated that alterations and modifications thereof will no doubt be come apparent to those skilled in the art. It is therefore intended that the following claims be interpreted as covering all such alterations and modifications as fall within the true spirit and scope of the invention.

We claim:

1. A balloon for a dilation procedure, the balloon having first and second adjacent body longitudinal portions the first body portion having a generally linear compliance curve to burst pressure and the second body portion having a stepped compliance curve characterized by a low pressure segment defined by a low inflation pressure range, said low pressure segment being generally collinear with a corresponding segment of the compliance curve of the first body portion which is defined by said low inflation pressure range, a transition segment during which the balloon expands rapidly relative to the first body portion and a high pressure segment during which the compliance curve of the second portion expands slowly relative to the transition region.

2. A balloon as in claim **1** wherein the balloon has a burst pressure of at least 16 atm.

3. A balloon as in claim **1** wherein when the balloon is inflated to a pressure of 6 atm the second body portion is on the low pressure segment of its compliance curve and when the balloon is inflated to 15 atm the second body portion is on the high pressure segment of its compliance curve.

4. A balloon as in claim **3** wherein the diameter of the second body portion at 6 atm is in the range of 2.35 –2.65 mm and the diameter of the second body portion at 15 atm is in the range of 2.75 to 4.75 mm.

5. A balloon as in claim **1** wherein the balloon further comprises a third body portion adjacent the second body portion so that the second body portion lies between the first and third body portions, the third body portion having a compliance curve which is generally linear to burst and generally collinear with the compliance curve of the first body portion to burst.

6. A balloon as in claim **5** wherein the lengths of the first and third body portions are substantially equal and the length of the second body portion is approximately twice the length of the first body portion.

7. A balloon as in claim **1** made of a thermoplastic polymer selected from the group consisting of polyesters, nylons, thermoplastic polyimides and thermoplastic polyurethanes, and wherein said thermoplastic polymer is a material which can provide a balloon wall strength of at least 18,000 psi.

8. A balloon as in claim **7** made of a polyester selected from poly(ethylene terephthalate) and poly(ethylene napthalenedicarboxylate).

9. A balloon as in claim **1** wherein the high pressure segment has a compliance curve according to which the balloon expands at a rate of no more than 0.1 mm/atm from 15 atm to burst.

10. A balloon as in claim **9** wherein according to said high pressure compliance curve the balloon expands at a rate no more than is no more than 0.06 mm/atm from 15 atm to burst.

11. A balloon as in claim **1** having a wall strength of at least 18,000 psi.

12. A balloon as in claim **11** wherein said wall strength is greater than 20,000 psi.

13. A method for preparing a balloon as in claim **1** wherein the balloon is blown in a mold having a configuration providing the first and second body portions of the balloon with different diameters, the second body portion diameter being greater than the first body portion, and then

shrinking the second body portion to a diameter approximately equal to the diameter of the first body portion by annealing the second body portion at a temperature and pressure which will cause the balloon material to shrink.

14. A method as in claim 13 wherein the annealing of said second body portion is accomplished by dipping the second body portion in a heated fluid while the first body portion is kept out of said fluid.

15. A method as in claim 13 wherein the mold configuration further provides the balloon with a third body portion adjacent the second body portion so that the second body portion is between said first and said third body portions.

16. A method as in claim 15 wherein the annealing of said second body portion is accomplished by dipping the second and third body portions in a heated fluid while the first body portion is kept out of said fluid, and then after the second body portion has shrunk to the diameter of the first body portion, the third body portion is heated and reblown to restore it to the diameter of the first and second body portions.

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,749,851

DATED : May 12, 1998

INVENTOR(S) : Lixiao Wang

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Col. 8, line 57, delete "is no more than".

Signed and Sealed this

Eighteenth Day of August, 1998

Attest:

Bruce Lehman

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks